Notice of Allowability	Application No.	Applicant(s)	
	09/559,344	NEGRIER ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	6 (OR REMAINS) CLOSED i) or other appropriate comm RIGHTS. This application is	n this application. If not included unication will be mailed in due course. THIS	e
1. This communication is responsive to amendment filed 7/2	2/04 and TD filed 9/13/04.		
2. X The allowed claim(s) is/are 1,3,4,9-12,15 and 16.		,	
3. The drawings filed on 27 April 2000 are accepted by the E	xaminer.		
 4. Acknowledgment is made of a claim for foreign priority u a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents 	e been received. e been received in Application	on No	
International Bureau (PCT Rule 17.2(a)).			
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	of this communication to file MENT of this application.	a reply complying with the requirements	
5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.			
 6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of 			
each sheet. Replacement sheet(s) should be labeled as such in			
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.			
Attachment(s)	_		
 Notice of References Cited (PTO-892) Dotice of Draftperson's Patent Drawing Review (PTO-948) 	_	nformal Patent Application (PTO-152) Summary (PTO-413),	
	Paper No.	/Mail Date	
 Information Disclosure Statements (PTO-1449 or PTO/SB/0 Paper No./Mail Date 	08), 7. ⊠ Examiner's	Amendment/Comment	
4. Examiner's Comment Regarding Requirement for Deposit		Statement of Reasons for Allowance	
of Biological Material	9.	 '	

Application/Control Number: 09/559,344

Art Unit: 1653

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Amy Purcell on October 4, 2004.

The application has been amended as follows:

IN THE SPECIFICATION:

On page 1, after the title of the invention and before "Subject of the Invention...", please insert the heading --INTRODUCTION--.

On page 3, line 1, before "The development of said DNA-construct was performed as follows:", please insert the following:

--BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates the cloning of the GPIIb promoter into the pcDNA3 vector, thereby producing the pcDNA3-GPIIb construct.

Application/Control Number: 09/559,344

Art Unit: 1653

Figure 2 demonstrates the generation of the pUT535-GPIIb construct, which contains a B-galactosidase reporter gene under the control of the truncated GPIIb promoter.

Figure 3 shows the transient B-galactosidase expression directed by the CMV and GPIIb promoter in HeLa cells (Panel A) and shows the transient B-galactosidase expression directed by the CMV and GPIIb promoter in HEL cells (Panel B).

Figure 4 shows the transient FIX production under CMV promoter control in HEL cells after PMA induction.

Figure 5 demonstrates transient production of FIX WT under CMV or GPIIb promoter control in HEL cells after PMA induction.

Figure 6 demonstrates FIX production under CMV promoter control in stably transfected HEL cells.

Figure 7 shows FIX production under GPIIb promoter control in stably transfected HEL cells.

Figure 8 demonstrates the correlation between FIX procoagulant activity and FIX antigen in the supernatants from HEL cells.

Figure 9a shows the stable expression of FIX (WT) in HEL cells without PMA induction. Figure 9b shows the stable expression of FIX (WT) in HEL cells with PMA induction.

Art Unit: 1653

Figure 10 demonstrates the ability of FIX (WT.I1) directed by the GPIIb promoter to increase FIX production in HEL cells.

Figure 11 shows the FIX coagulant activity in the supernatant of HEL cells transfected with GPIIb-FIX(WT.I1) construct after PMA induction.

DETAILED DESCRIPTION—

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer October 4, 2004

JON WEBER

SUPERVISORY PATENT EXAMINER